A pragmatic trial with randomisation embedded in usual practice and staged consent within the Born in Bradford's Better Start (BiBBS) birth cohort: evaluation of a continuity of carer midwife-led model in Bradford

Josie Dickerson[1], Rachael Moss[1], Maria Bryant[2] and Tracey Bywater[1]

[1] Born in Bradford, Bradford Institute for Health Research; [2]Department of Health Sciences, University of York

Background and Aims

What is the MCC model?

- Delivers consistency in regard to the midwife that provides a woman with care across their pregnancy.
- Evidence suggests CoC reduces risk of additional interventions during labour and leads women to have increased satisfaction.

Aims:

- Evaluate the impact of the MCC intervention
  (in a vulnerable population using a pragmatic RCT)
- Support midwifery to allow randomisation to become embedded in usual care

Intervention

Intervention: MCC		Traditional Care
Flexible (in terms of frequency, duration and location) midwife appointments		Set number of midwife appointments
Flexible length of support postnatally		Discharged 2 weeks postnatally
Caseload of 30-35 women per midwife		Caseload of approximately 100 women per midwife
Funded through the Better Start Bradford programme, Bradford Teaching Hospitals Foundation Trust and the RIC programme		

The Born in Bradford Better Start (BiBBS) Cohort

A novel interventional cohort

Created to evaluate early years interventions using pragmatic RCTs and quasi-experimental designs

Women are recruited in pregnancy

This data is used to evaluate the impact of early years interventions

Sample: a representative sample of ethnically diverse families (61% Pakistani heritage, over 50 languages spoken) who live in areas of deprivation.

Consent to the BiBBS Cohort

Our population is seldom heard and as such this gives our cohort an advantage

Within our cohort we have high retention rates because we do not demand frequent measurements from participants

Interventions are never withheld from participants - where it is neither ethical nor feasible, randomisation methods will not be used

Participants consent for their information to be used to evaluate projects and for them to be randomised into interventions where there is not enough capacity for everyone to attend

Consent to the BiBBS Cohort

You may be offered the chance to take part in Better Start Bradford projects. If lots of families want to take part in projects, there may not be enough places for everyone. If this happens, families may be selected for projects by chance (randomly), like using the toss of a coin. If your family are not selected to take part in a project we may compare your information with families who have been selected to take part in a project.

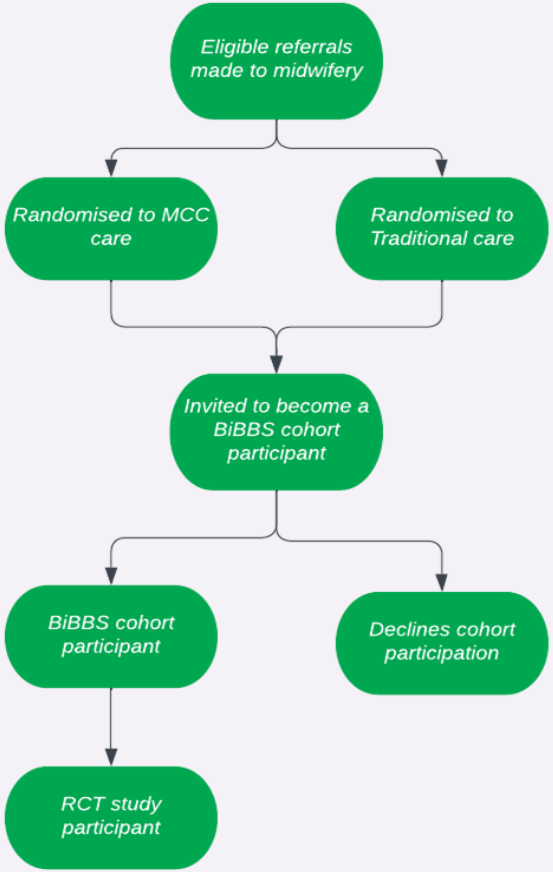
Study Population

- The demand for the MCC service outweighs capacity
- Midwifery services were allocating women to MCC and traditional care initially in an ad hoc way
- We therefore worked with the midwifery team to help them move from randomising in an ad hoc way to embed point-of-care randomisation at the time of referral to midwifery services
- A 3 month internal pilot (Apr-Jun 2022) tested the feasibility of this process using RAG rated criteria
- For MCC we obtained additional ethical approval for the randomisation in practice

Study Design

- Women in the RCT are those who:
  - Were randomised to receive either MCC or traditional midwifery care at point of pregnancy
  - Then consented to being in the BiBBS cohort (both MCC and traditional care women)

- Outcomes were collected from linked health and BiBBS research data so there is no additional burden to women or potential loss to follow up



Results

- Thus far, we have established that point-of-care randomisation has been deemed feasible based on:
  - The proportion of eligible women randomised
  - An acceptable allocation ratio (was 4:5 (MCC:Traditional care), now 1:1)

- To date, 572 women have been randomised
- Chosen 2 independent primary outcomes (are powered to detect a difference):
  1. Spontaneous vaginal deliveries
  2. Postnatal depression at 6-10 weeks

Conclusions

- The BiBBS interventional cohort has allowed a pragmatic RCT to be conducted.
- This RCT examines the ability of an evidence based intervention, the MCC model to reduce inequalities in women:
  - From ethnic minority backgrounds
  - Living in deprivation
- Study findings from our RCT are due in Spring 2025.